

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE ASACOL ANTITRUST LITIGATION

Civil Action No. 1:15-cv-12730-DJC

This Document Relates To:

FILED UNDER SEAL

All End-Payor Actions

**END-PAYOR PLAINTIFFS' MEMORANDUM IN
OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Plaintiffs challenge Warner Chilcott’s business decision to stop marketing and selling its blockbuster ulcerative colitis drug, Asacol 400mg, while simultaneously introducing and marketing a “new” 400mg tablet-in-a-capsule as its replacement. This product switch involved only two changes: an inactive ingredient, DBP, was replaced with DBS in the Asacol tablet coating; and the tablet was enclosed in a capsule. Warner Chilcott called its “new” product Delzicol. That was in March 2013, four months before Warner Chilcott’s patents on the Asacol tablets were set to expire on July 30, 2013.

Defendants claim that Warner Chilcott launched a “safer” capsule product to address an FDA request to remove DBP from Asacol, but when Defendants substituted DBS for DBP in the United Kingdom, where they faced no patent cliff,¹ they kept selling the 400mg tablet as “Asacol,” with no patent-protected capsule addition. They did the same in the United States with Asacol HD, an 800mg version of Asacol that also faced no patent cliff. Patients were outraged at the switch and were plagued with problems swallowing the formulation. This hard-switch “product hopping” scheme worked. Defendants maintained monopoly profits by sacrificing their largest-selling Asacol 400mg product for Delzicol—an inferior product with a longer period of patent protection against generic competition. As Warner Chilcott’s CEO and President Roger Boissonneault said publicly about the hard-switch and those in the industry: “they’re all familiar with what’s going on.” Pls.’ Statement of Facts (“PSOF”) ¶ 48.

This Court previously held that Plaintiffs adequately pled claims for monopolization and it rejected Defendants’ previous summary judgment attacks on causation, anticompetitive effect,

¹ “Patent cliff” refers to the recognized pharmaceutical industry phenomenon whereby sales of a brand drug “fall off a cliff” when generic entry occurs after patent expiration. *See, e.g.* <http://www.investopedia.com/terms/p/patent-cliff.asp>.

relevant market, and preemption. *In re Asacol Antitrust Litig. (Asacol I)*, No. 15-cv-12730-DJC, 2016 WL 4083333 (D. Mass. July 20, 2016); *In re Asacol Antitrust Litig. (Asacol II)*, 323 F.R.D. 451 (D. Mass. 2017). Now Defendants seek summary judgment of the entire case by resurrecting their own manufactured idea of what “coercion” means in antitrust law. They also target a number of class-specific state law claims that are not brought, and have never been brought, on behalf of the individual named Plaintiffs themselves. Neither argument allows them to dispose of this case.

Defendants’ primary argument is based on an erroneous premise of law. As Warner Chilcott would have it, to prove anticompetitive effect in an antitrust case involving market foreclosure, plaintiffs must not just show the elimination of competition and consumer choice, but must also show that the elimination of consumer choice forced consumers to *only* certain specific products.² That is not the law. Defendants coerced patients by eliminating consumer choice “rather than persuad[ing] them on the merits” when they withdrew Asacol 400 and introduced an inferior gimmick product in its place. *New York ex rel. Schneiderman v. Actavis PLC (Namenda)*, 787 F.3d 638, 654 (2d Cir.), *cert. dismissed*, 136 S. Ct. 581 (2015). The court decided that already. *Asacol II*, 323 F.R.D. at 487 (“The Plaintiffs’ theory is in line with the Second Circuit’s decision in *In re Namenda*, 787 F.3d at 652.”). Nothing in the First Circuit’s Rule 23(f) opinion disturbed that ruling.

Nor is Defendants’ “coercion” argument relevant to antitrust injury. For the individual third-party payor (“TPP”) plaintiffs, it does not matter which *specific* Asacol HD and Delzicol prescriptions would have been generic Asacol 400 prescription but-for Defendants’ misconduct or that some small number would have remained on Asacol HD or Delzicol; it only matters that

² Mem. of Law in Supp. of Defs.’ Mot. for Summ. J., *In re Asacol Antitrust Litig.*, No. 1:15-cv-12730, at 1-12 (D. Mass. May 21, 2019), ECF No. 793 (“D. Br.”).

each Plaintiff paid for *at least one* Asacol HD or Delzicol prescription that would have been a cheaper generic Asacol 400 purchase but for Defendants' misconduct.³

Plaintiffs have substantial evidence capable of proving anticompetitive effect and antitrust injury at trial. *See* Sections I.A-B. The named Plaintiffs each paid for a number of independent Asacol HD and Delzicol prescriptions and, even putting aside the wealth of other qualitative and circumstantial evidence showing anticompetitive effect and antitrust injury, the simple math shows there is *at least* a 99.8% probability of injury for each named Plaintiff. PSOF ¶¶ 100-05. Defendants do not engage this evidence; instead, they build a strawman by broadly mischaracterizing the First Circuit's *class certification* opinion in this case to hold that individual testimony is the only way to prove anticompetitive effect and antitrust injury in an antitrust case involving market foreclosure, even when the plaintiff parties are TPPs, not consumers. Defendants attempt to rewrite *Asacol* but their reading cannot be squared with Supreme Court precedent and numerous other First Circuit cases, both before and after the *Asacol* opinion.

Defendants' second argument targets a variety of state law claims that are not brought on behalf of individual named Plaintiffs. Plaintiffs confirmed with Defendants before this briefing that named Plaintiffs had only four state claims on their own behalf: Minnesota, New Hampshire, Wisconsin, and Florida.⁴ Defendants attack three, Minnesota, New Hampshire, and Florida. They argue: (1) the redaction of personal patient ID information in outdated Teamsters and Minnesota Laborers data from almost two years ago somehow renders it categorically impossible

³ *In re Nexium Antitrust Litig. (Nexium I)*, 777 F.3d 9, 27 (1st Cir. 2015) ("Paying an overcharge caused by the alleged anticompetitive conduct on a single purchase suffices to show – as a legal and factual matter – impact or fact of damage.") (citations omitted); *Asacol II*, 323 F.R.D. at 476, 478, 481.

⁴ Plaintiffs have submitted a form of Stipulation of Dismissal to Defendants for their approval. Once Defendants respond, Plaintiffs will seek the voluntary dismissal of Teamsters. Teamsters' claims on its own behalf arise under New Hampshire law and it is the only named Plaintiff with New Hampshire claims. Thus, the New Hampshire/Teamsters arguments are moot.

to prove injury in New Hampshire and Minnesota respectively, and (2) NECA-IBEW cannot bring a Florida claim, despite purchases there, because “it is not a Florida resident[.]” D. Br. at 17-18. These arguments fail. *First*, Plaintiffs have collected unredacted supplemental purchase data that shows independent purchases and a straightforward application of Dr. Conti’s generic erosion and pricing yardsticks mathematically shows that injury to Minnesota Laborers is virtually certain. *See* Section I.B. *Second*, Defendants are simply wrong in their assertion that the Florida Deceptive and Unfair Trade Practices Act does not provide a remedy to out-of-state residents who are injured in Florida. *Renaissance Cruises, Inc. v. Glassman*, 738 So. 2d 436, 438-39 (Fla. Dist. Ct. App. 1999).

SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate only when the record reveals “no genuine dispute as to any material fact and [that] the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). When reviewing a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Rather, the evidence submitted must be considered in the light most favorable to the nonmoving party, drawing all reasonable inferences in its favor. *Navarro v. Pfizer Corp.*, 261 F.3d 90, 94 (1st Cir. 2001).

ARGUMENT

Section 2 of the Sherman Act makes it illegal to “monopolize, or attempt to monopolize ... any part of the trade or commerce” among several states. *Diaz Aviation Corp. v. Airport Aviation Servs., Inc.*, 716 F.3d 256, 265 (1st Cir. 2018) (alteration in original) (citation omitted). Plaintiffs’ state law claims are construed in parallel with Sherman Act Section 2. *See In re Asacol Antitrust Litig. (Asacol III)*, 907 F.3d 42, 49 (1st Cir. 2018). To prove monopolization,

Plaintiffs must show Warner Chilcott engaged in exclusionary conduct to protect its monopoly position. *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 21 (1st Cir. 1990). Exclusionary conduct consists of “the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (citation omitted). “Coercion” from exclusionary conduct is established when defendants eliminate consumer choice. *See United States v. Microsoft Corp.*, 253 F.3d 34, 60-77 (D.C. Cir. 2001) (upholding findings of anticompetitive effect for various Microsoft practices that eliminated consumer choice); *Asacol I*, 2016 WL 4083333, at *10 (“[W]ell-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition.”) (citation omitted); *Nat’l Collegiate Athletic Ass’n v. Bd. of Regents*, 468 U.S. 85, 116-17 (1984) (affirming judgement where NCAA restricted output of [market 1] televised games to increase [market 2] live attendance revenues). “[W]hen a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act.” *Namenda*, 787 F.3d at 654 (emphasis omitted) (citation omitted); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1382 (Fed. Cir. 1998) (upholding verdict against manufacturer of biopsy gun that modified its product to prevent compatibility with competitor replacement needles).

I. Defendants “coerced” Plaintiffs by eliminating generic competition and consumer choice.

There is a genuine dispute about whether Warner Chilcott combined the withdrawal of Asacol 400mg in March 2013—only months before the drug’s “patent cliff”—with the introduction of the “new” Delzicol to thwart generic competition. The court has already ruled on

this. *Asacol II*, 323 F.R.D. at 488-89. Denied the opportunity to purchase generic Asacol 400, many purchasers purchased Asacol HD and Delzicol instead—Defendants’ other patent protected drugs. The proper questions in front of the court now are: (1) whether Plaintiffs have adduced sufficient evidence of anticompetitive effect to go to a jury, and (2) whether there is evidence in the record from which a jury could conclude that each TPP named Plaintiff in this case was overcharged on at least a *single* Asacol HD or Delzicol purchase. The answer to both questions is yes. Defendants’ coercion argument is largely a confused conflation of the anticompetitive effect element of an antitrust claim (discussed in Section I.A) and the antitrust injury and cause-in-fact elements of an antitrust claim (discussed in Section I.B). Defendants’ claim that proof of injury to the TPP named Plaintiffs can only come in the form of individual testimony from thousands of consumer witnesses is contrary to precedent, logic, the record, and basic mathematics.

A. Defendants’ misconduct eliminated consumer choice.

Defendants cannot dispute that they withdrew Asacol 400 from the market or that the court already held Plaintiffs adduced sufficient evidence that Defendants’ withdrawal foreclosed generic competition. Instead, hidden behind the guise of a repackaged “coercion” argument, Defendants try and argue that even if generic entry had occurred, Plaintiffs lack evidence that the majority of Asacol HD and Delzicol prescriptions would have been the cheaper generic Asacol 400 and the named Plaintiffs were overcharged at least once. Plaintiffs do not need to interview every single consumer to establish those facts; the existing evidence is overwhelming.

[REDACTED]

[REDACTED] PSOF ¶ 25.

[REDACTED]

[REDACTED]

[REDACTED] PSOF ¶ 40. He publicly discussed the anticipated arrival of generic competition and the hard-switch scheme to avoid it: “[T]he generic company doesn’t even get launched because the reference product will be Delzicol. . . . There won’t be any Asacol out there.” PSOF ¶¶ 42-43. [REDACTED]

[REDACTED] PSOF ¶ 29.

[REDACTED]

[REDACTED]

[REDACTED] PSOF ¶ 27. [REDACTED]

[REDACTED] PSOF ¶ 28. Defendants argue that Plaintiffs have no evidence of “coercion,” but “coercion” was the entire point of Warner Chilcott’s hard-switch. PSOF ¶¶ 23-57, 89. Warner Chilcott would not have abandoned its blockbuster Asacol 400 drug *unless* it would extend monopoly profits in the Asacol HD and Delzicol lines. PSOF ¶ 47.

Warner Chilcott repeatedly admitted that Asacol 400 prescriptions would likely *remain* Asacol 400 prescriptions barring some action on their part to take the choice away from patients. PSOF ¶¶ 16-19, 51-87. Mr. Boissonneault acknowledged: “[W]hen someone is put on Asacol for their ulcerative colitis, it is likely that they [are] put on the product [when they are] 20 to 30 years old, and they are probably going to be taking that product for the rest of their lives” PSOF ¶ 17. John Goll, another Warner Chilcott employee, explained: [REDACTED]

[REDACTED]

[REDACTED] PSOF ¶ 19. Defendants’ own medical experts testified to the same. PSOF ¶¶ 16, 57.

Defendants' actions prevented generic Asacol 400 entry at the expense of end-payors. PSOF ¶¶ 50-57, 59-87, 100-06. It is undisputed that after Warner Chilcott withdrew Asacol 400 from the market, all end-payors lost the opportunity to purchase Asacol 400 and its cheaper generic equivalents.⁵ That is the "coercion" at issue in this case; that is the consumer choice that Warner Chilcott destroyed; and that is an anticompetitive effect.

The case law outlining the contours of "coercion" in an antitrust market foreclosure case is well-established and uniformly goes against Defendants' novel construction here. *See, e.g., Namenda*, 787 F.3d at 654 (defining "coercion" by reference to consumer choice eliminated by product withdrawal); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 603-04 (1985) (upholding jury verdict for plaintiff where the defendant's decision to withdraw multi-mountain ski pass deprived consumers of choice); *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665, 681-82 (E.D. Pa. 2014) (analyzing "coercion" in monopolization foreclosure case by reference to restrictions on "freedom of consumer choice" that "prevent[ed] consumer choice and reduce[d] the market's ambit"); *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 422 (D. Del. 2006) (same).⁶ These cases, like all others in antitrust law, focus the anticompetitive effect inquiry on whether there has been an elimination of consumer choice or a decrease in consumer welfare. Defendants are trying to pin new requirements on a very well-established principle of antitrust law. *See, e.g., Associated Gen. Contractors of Cal., Inc. v. Cal.*

⁵ PSOF ¶ 51; Defendants' economist, J. Douglas Zona, conceded "coercion." Zona Tr. 26:23-27:2

([REDACTED]).

⁶ *Cf. Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1000 (9th Cir. 2010) ("Absent some form of coercive conduct by the monopolist, the ultimate worth of a genuine product improvement can be adequately judged only by the market itself."); *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 n.39 (2d Cir. 1979) ("Thus, the situation might be completely different if . . . Kodak had ceased producing film in the 126 size, . . ."); *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) (granting motion to dismiss because "there is no allegation that AstraZeneca eliminated any consumer choices").

State Council of Carpenters, 459 U.S. 519, 528 (1983) (“Coercive activity that prevents its victims from making free choices between market alternatives is inherently destructive of competitive conditions and may be condemned even without proof of its actual market effect.”); *FTC v. Ind. Fed’n Dentists*, 476 U.S. 447, 459 (1986) (restrictive agreement that “limit[ed] consumer choice by impeding the ‘ordinary give and take of the market place,’ cannot be sustained under the Rule of Reason”) (citation omitted); *Blue Shield of Va. v. McCready*, 457 U.S. 465, 481-84 (1982) (upholding antitrust claim where plaintiff psychotherapy patient was “coerced” by defendant insurer’s policy of reimbursing for psychiatrist treatment but not psychologist treatment).⁷

Other than a mischaracterized reading of the First Circuit’s *Asacol* class certification opinion, Defendants only cite one other case in support of their “coercion” creation: *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co. (Doryx)*, 838 F.3d 421 (3d Cir. 2016). *Doryx* supports Plaintiffs. In *Doryx*, the Third Circuit affirmed the district court’s finding of no anticompetitive effect because the generic competitor *was not foreclosed from the market*; in other words, unlike here, consumer choice was not eliminated. *Id.* at 438-39. The Third Circuit

⁷ Cf. *Sterling Merch., Inc. v. Nestle, S.A.*, 656 F.3d 112, 125-26 (1st Cir. 2011) (rejecting antitrust claim where evidence showed no impact to “consumer access and choice”); *Ross v. Bank of Am., N.A. USA*, 524 F.3d 217, 224 (2d Cir. 2008) (“The reduction in choice and diminished quality of credit services to which the cardholders claim they have been subjected are present anti-competitive effects....”); *LifeWatch Servs. v. Highmark Inc.*, 902 F.3d 323, 340-41 (3d Cir. 2018) (upholding antitrust claim where patients were “induced” into outpatient cardiac monitor treatment by defendant insurer’s policy of refusing reimbursement for telemetry monitoring); *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 789-90 (6th Cir. 2002) (upholding jury verdict where there was evidence defendant’s actions “caused higher prices and reduced consumer choice, both of which are harmful to competition”); *Four Corners Nephrology Assocs., P.C. v. Mercy Med. Ctr. of Durango*, 582 F.3d 1216, 1224 (10th Cir. 2009) (finding valid procompetitive justification where exclusive dealing contract actually resulted in *additional* consumer choice); *Palmyra Park Hosp., Inc. v. Phoebe Putney Mem’l Hosp.*, 604 F.3d 1291, 1303 (11th Cir. 2010) (holding “higher prices and fewer choices for consumers” are “precisely the type of harm that we allow plaintiffs to vindicate through the antitrust laws”); *Cal. Ass’n of Realtors v. PDFfiller, Inc.*, No. 16-cv-11021, 2018 WL 1403330, at *10 (D. Mass. Mar. 2) (restrictions on consumer choice sufficient to allege antitrust injury), *report & recommend’n adopted* by 2018 WL 1399296 (D. Mass. Mar. 19, 2018).

expressly distinguished the *Doryx* situation from cases where there was elimination of consumer choice, such as *Namenda*. *Id.* at 440 (noting *Namenda*'s distinction that *Doryx* was "an example of a situation in which there was no evidence of consumer coercion, because generics 'had already entered the market at the time of defendants' product reformulation'" (citation omitted). Here, like *Namenda* and unlike *Doryx*, consumers were foreclosed from the cheaper generic product.

To be sure, under the rule of reason, Defendants will have the opportunity at trial to try and balance the total elimination of the Asacol 400 choice for consumers with procompetitive justifications, but this Court has already held (1) Defendants lack evidence for several of their "justifications," and (2) Plaintiffs have sufficient evidence to rebut Defendants' justifications as pretextual. *Asacol II*, 323 F.R.D. at 487. Defendants are simply incorrect that Plaintiffs cannot prove anticompetitive effect (or "coercion"). Defendants are also incorrect that Plaintiffs cannot prove antitrust injury and cause-in-fact, which are analytically separate from anticompetitive effect (or "coercion"). *In re Nexium Antitrust Litig. (Nexium II)*, 842 F.3d 34, 60 (1st Cir. 2016).

B. Plaintiffs can prove antitrust injury.

In support of their misguided and self-created definition of "coercion," Defendants rely almost exclusively on a broad mischaracterization of the First Circuit's class certification opinion. Defendants' reliance is misplaced; their reading of the First Circuit's *Asacol* decision is inconsistent with all of the case law discussed above—including binding Supreme Court precedent—and it is also inconsistent with the First Circuit's own cases, including *In re Celexa & Lexapro Mktg. & Sales Practices Litig. (Lexapro)*, 915 F.3d 1 (1st Cir. 2019), which was authored shortly after the *Asacol* opinion, by the same judge. Plaintiffs here can prove antitrust

injury in the form of overcharges, and can prove the causal link between those overcharges and Defendants' foreclosure of generic Asacol 400 competition.

“Paying an overcharge caused by the alleged anticompetitive conduct on a single purchase suffices to show—as a legal and factual matter—impact or fact of damage.” *Nexium I*, 777 F.3d at 27 (citation omitted); *see Asacol II*, 323 F.R.D. at 476, 478, 481. “[A]ntitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset.” *Nexium I*, 777 F.3d at 27. For almost a century, it has been blackletter antitrust law that where a plaintiff proves a loss, and a violation by defendant of the antitrust laws of such a nature as to be likely to cause that type loss, “the jury, as the trier of the facts, must be permitted to draw from this circumstantial evidence the inference that the necessary causal relation exists.” *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 697 (1962) (citation omitted) (approving the Ninth Circuit's reliance on *Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251 (1946), *Story Parchment Co. v. Paterson Parchment Co.*, 282 U.S. 555 (1931), and *Eastman Kodak Co. of N.Y. v. S. Photo Materials Co.*, 273 U.S. 359 (1927)); *see also In re Neurontin Mktg. & Sales Practices Litig. (Kaiser)*, 712 F.3d 21, 45 (1st Cir. 2013) (“Once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, the burden shifts to the defendant to rebut this causal inference.”) (citation and internal quotation marks omitted).⁸

⁸ *See also Haverhill Gazette Co. v. Union Leader Corp.*, 333 F.2d 798, 805-07 (1st Cir. 1964) (vacating judgment condemned as “too favorable treatment of a deliberate wrongdoer” where the trier of fact “put [the] burden on” plaintiff “to eliminate all proper causes for the [anticompetitive harm] to the extent of affirmatively showing that the illegal causes were the sole or most substantial”); *Momand v. Universal Film Exchanges, Inc.*, 172 F.2d 37, 42 (1st Cir. 1948) (causation “in an anti-trust suit, covering as it must many imponderables, rigid standards of precise proof would make a plaintiff's task practically hopeless”); *Automatic Radio Mfg. Co. v. Ford Motor Co.*, 390 F.2d 113, 117 (1st Cir. 1968) (same). “Intervening cause” is Defendants' burden of proof. *Kaiser*, 712 F.3d at 45.

Thus, a *prima facie* case of cause-in-fact can be inferred from the exclusionary conduct and the harm that naturally flows from such conduct:

We may infer causation when exclusionary conduct is aimed at producers of nascent competitive technologies as well as when it is aimed at producers of established substitutes. Admittedly, in the former case there is added uncertainty, inasmuch as nascent threats are merely *potential* substitutes. But the underlying proof problem is the same—neither plaintiffs nor the court can confidently reconstruct a product’s hypothetical technological development in a world absent the defendant’s exclusionary conduct. To some degree, “the defendant is made to suffer the uncertain consequences of its own undesirable conduct.”

Microsoft, 253 F.3d at 79 (citation omitted).⁹

The analysis of antitrust injury and the causal link for Plaintiffs here is far more straightforward than Defendants paint it. Plaintiffs have adduced evidence that generic entry would have occurred earlier but for Defendants’ misconduct; that is not up for debate in this motion, the Court has decided that. The question left is: had generic Asacol 400 entered the market, do Plaintiffs have evidence that they would have made at least a single purchase at a lower price than they paid for Asacol HD or Delzicol? The answer is yes; there is ample direct and circumstantial evidence capable of proving injury and cause-in-fact for Plaintiffs.

Plaintiffs’ expert, Dr. Rena Conti, offers an opinion on antitrust impact and aggregate damages based on a commonly used “yardstick” methodology that is identical to the methodologies accepted by numerous other courts in generic suppression antitrust litigation in this Circuit and elsewhere. *See, e.g., Asacol II*, 323 F.R.D. at 467-70 (denying Defendants’ motion to exclude Dr. Conti’s testimony); *Nexium I*, 777 F.3d at 26 (approving plaintiffs’ yardstick methodology). Dr. Conti’s overcharge pattern modeling shows the empirical

⁹ *See also In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 101 (2d Cir. 2017) (“[E]ven at summary judgment, an antitrust plaintiff may be entitled to a presumption of causation where the anticompetitive conduct ‘is deemed wrongful because it is believed significantly to increase the risk of a particular injury’ and that injury occurred.”) (citation omitted); *BCS Servs. v. Heartwood 88, LLC*, 637 F.3d 750, 758 (7th Cir. 2011) (same).

likelihood that any given Asacol HD or Delzicol prescription in the actual world *would have been* a cheaper Asacol product had Defendants not crushed generic competition before it could begin. PSOF ¶ 100. In her analysis of Scenario 1.A, Dr. Conti shows that about 73.4% of Delzicol prescriptions would have switched to the generic Asacol 400 product, and 28.1% of Asacol HD prescriptions would have switched to the lower-priced brand Asacol 400 product or the generic Asacol 400 product. PSOF ¶¶ 102 (Ex. 31; Ex. 96, Rosenthal Decl. at ¶ 8¹⁰).

The Court and the jury can look at the multitude of independent Asacol HD and Delzicol purchases that the named Plaintiffs have and determine the mathematical likelihood that *at least one* of those purchases would have been a cheaper Asacol prescription but for Defendants' misconduct. To borrow Dr. Rosenthal's "coin-flip" explanation:

To see how this probability analysis works, take first a simple example – the toss of a fair coin. If there is a single coin toss, we know that the chance the coin does not land on "heads" is 50%. If we toss the coin twice the chance that the coin shows heads neither time is: $50\% * 50\% = 25\%$. If we toss the coin three times, the chance that the coin never shows heads is: $50\% * 50\% * 50\% = 12.5\%$. With only seven coin tosses, there is less than a 1% chance of never seeing heads. We can use this same logic to ask how many patients a third-party payer would need to have a *de minimus* chance of being uninjured.

PSOF ¶ 102 (Ex. 96, Rosenthal Decl. at 6).

Application of this mathematical analysis to the named Plaintiffs' purchase data shows the quantitative likelihood of injury is far beyond the "more likely than not" threshold required in a civil case. Applying Dr. Conti's yardsticks and the same probability analysis outlined by the First Circuit and Dr. Rosenthal in *Lexapro*, the

¹⁰ The Delzicol switcher ratio is calculated as the sum of Ex. 31, Conti Rep. Attachment C.10.a Column 9 divided by the sum of Attachment C.7 Column 5, or the but-for number of prescriptions switching to generic Asacol 400 divided by the actual number of Delzicol prescriptions. The Asacol HD switcher ratio is calculated as the sum of Attachment C.7 Column 9 divided by Attachment C.7 Column 4, or the but-for number of prescriptions that would have switched to the brand or generic version of Asacol 400 divided by the actual number of Asacol HD prescriptions.

likelihood of injury, *i.e.*, at least one overcharge, for the named Plaintiffs in this case is above 99.8%. Using Judge Kayatta's language in *Lexapro*, "the odds that [a TPP] was not harmed" are "likely infinitesimal (assuming the prescriptions were independent of one another)." *Lexapro*, 915 F.3d at 13.

- In the supplemental data¹¹ through July 12, 2017 alone, Wisconsin Masons has 5 independent Delzicol purchasers and 3 independent HD purchasers, all purchasing in Wisconsin. **Wisconsin Masons' likelihood of injury is 99.95%.**¹²
- In the supplemental data through June 30, 2017 alone, NECA-IBEW has 5 independent Delzicol purchasers in Wisconsin, 4 independent HD purchasers in Florida, and 3 independent HD purchasers in Wisconsin. **NECA-IBEW's likelihood of injury is 99.99%.**¹³
- In the supplemental data covering only up until June 30, 2015, MN Laborers has 2 independent Delzicol purchasers in Minnesota and 11 independent HD purchasers in Wisconsin and Minnesota. **MN Laborers' likelihood of injury is 99.8%.**¹⁴

Importantly, these mathematical probabilities conservatively assume that each independent purchaser only purchases once.¹⁵ For every subsequent purchase, the probability of a generic Asacol 400 transaction in the but-for world can only increase

¹¹ Defendants make much of the fact that the purchase data Plaintiffs originally produced over two and a half years ago, in response to the contours of Defendants' own discovery requests, was redacted for specific patient identification. D. Br. at 17-18. Defendants never requested unredacted data; neither party believed it was necessary at that stage in the case.

¹² Compare Ex. 31, Conti Rep. (see n.10 *supra*) and Ex. 96 Rosenthal Decl. Table 1 to Ex. 98, WI Masons supplemental data: independent purchasers shown in Column U, identified by the last four digits 7020, 2242, 1463, 8905, 0600 (Delzicol purchasers) and 4312, 2630, 9508 (Asacol HD purchasers).

¹³ Compare Ex. 31, Conti Rep. (see n.10 *supra*) and Ex. 96, Rosenthal Decl. Table 1 to Ex. 99, NECA supplemental data: independent purchasers shown in Column R, identified by the last four digits 2958, 2530, 2864, 2722, 8829 (Delzicol purchasers) and 3997, 4023, 8250, 3813, 2295, 2300, and 4183 (Asacol HD purchasers).

¹⁴ Compare Ex. 31, Conti Rep. (see n.10 *supra*) and Ex. 96, Rosenthal Decl. Table 1 to Exs. 100-01, MN Laborers supplemental data: independent purchasers shown in Column 5 (Unique Member ID), identified by the last four digits 8460, 1101 (Delzicol purchasers) and 5301, 1001, 3002, 0402, 8801, 0501, 9601, 3701, 1101, 3107, and 1801 (Asacol HD purchasers). Pharmacy location is confirmed in Minnesota and Wisconsin by cross-checking the NABP pharmacy code for independent purchasers identified in Ex. 101 against the NABP code and pharmacy state in Ex. 100.

¹⁵ Though it has no quantified impact on the probability analysis, it is worth noting that every single one of the independent purchasers identified above that was purchasing a product prior to the hard-switch was purchasing Asacol 400.

because of automatic generic substitution laws and ways managed care organizations encourage consumers to try a generic drug over a brand drug at least once. PSOF ¶ 106.

In addition to the quantitative evidence outlining the probability of injury and the qualitative evidence showing that even Warner Chilcott knew consumers wanted to stay on Asacol 400, the record is also replete with direct complaints from consumers that were forced off of Asacol 400. [REDACTED]

[REDACTED] PSOF ¶¶ 59-87. [REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

PSOF ¶ 86 (Exs. 68-71). Defendants' introduction of Delzicol in the place of Asacol 400 [REDACTED]

[REDACTED] PSOF ¶¶ 59-87. [REDACTED]

[REDACTED]

[REDACTED] PSOF ¶¶ 66-67. [REDACTED]

[REDACTED] PSOF ¶¶ 90-99.

Defendants, of course, will disagree with the underlying yardsticks in Dr. Conti's methodology and may contest the probabilities of injury at trial. They will certainly attempt to explain away the rows and rows of consumer complaints that flooded in when Warner Chilcott forced everyone off of Asacol 400. They may even try to convince the jury that generic drugs are more expensive than brand drugs. The jury will have the opportunity to weigh the credibility of whatever admissible evidence Defendants can try and muster in support of these claims. That merits dispute warrants the denial of Defendants' motion. Read in the light most favorable to non-movant Plaintiffs, the cumulative evidence of injury is sufficient to sustain a jury verdict on antitrust injury and cause-in-fact under the "more likely than not" standard.

Defendants' new "coercion" standard rests entirely upon out-of-context quotes from *Asacol*, but they do not cite, much less discuss, *Lexapro*, *In re Neurontin Mktg. & Sales Practices Litig. (Neurontin)*, 712 F.3d 60 (1st Cir. 2013), or *In re Pharm. Indus. Average Wholesale Price Litig. (AWP)*, 582 F.3d 156 (1st Cir. 2009)—all on-point First Circuit precedents preceding and following *Asacol*. Defendants also omit one crucial fact in the course of their total reliance on *Asacol*: this case no longer includes consumer plaintiffs and it no longer involves TPPs without at least a "handful" of independent purchases (to the extent any such TPPs even exist).¹⁶ The First Circuit's entire discussion in *Asacol* was predicated on the existence of some number of uninjured consumers. On the record before it, the First Circuit found that it was not feasible to distinguish which *particular* individual consumers were injured and which were uninjured. *Asacol III*, 907 F.3d at 51 ("Plaintiffs' class nevertheless includes consumers who would have continued to purchase a brand drug for various reasons, even if a

¹⁶ See *Lexapro*, 915 F.3d at 14 ("[Plaintiff's] clinical and statistical evidence, if believed, could establish causation and injury at least for any TPP who paid for more than a handful of different patients' prescriptions.").

cheaper, generic version had been available.”). To borrow again from Dr. Rosenthal’s coin-flip example, a consumer only gets one “flip” of the coin to show statistical probability of injury and, importantly, Plaintiffs here did not dispute that there would be some small percentage of consumers who flipped the coin and came up “uninjured,” *i.e.*, “consumers who would have continued to purchase a brand drug for various reasons, even if a cheaper, generic version had been available.” *Id.*

A TPP “who paid for more than a handful of different patients’ prescriptions,”¹⁷ on the other hand, gets to “flip the coin” for every independent purchaser that it covers. Defendants are trying to apply *Asacol*’s consumer reasoning to TPPs, but such a reading would place *Asacol* squarely at odds with *Lexapro*, *Neurontin*, *Kaiser*, and *AWP*.

In *Lexapro*, the First Circuit expressly distinguished proof of consumer injury in *Asacol* from proof of TPP injury in *Lexapro*. Regarding proof of injury to a TPP, the *Lexapro* court explained: “The statistical proof in this instance is being used only to prove that a group of prescriptions likely includes at least one that a certain activity caused, and it is then being utilized to estimate the percentage of such causally connected prescriptions in that group.” *Lexapro*, 915 F.3d at 13 n.9. That is precisely what Plaintiffs are doing now with TPP injury proof. Each TPP has a group of independent prescriptions and the statistical proof, outlined above, is being utilized to estimate whether there is at least one overcharge prescription within that group of independent prescriptions. *Lexapro* goes on to expressly distinguish this use of statistical evidence in the TPP context from the consumer evidence at issue in *Asacol*: “[Plaintiff] Painters proposes no use of the statistical data to prove that [defendant] Forest’s off-label marketing caused *any particular prescription to be written*.” *Id.* (citing *Asacol III*, 907 F.3d

¹⁷ *Lexapro*, 915 F.3d at 14.

at 54) (emphasis added). In the First Circuit’s view, to determine particularized *consumer* injury on the *Asacol* record, it was necessary to determine whether the consumer’s particular prescription would or would not have been Asacol 400, but the TPP analysis is different. For TPPs, like Wisconsin Masons, NECA-IBEW, and MN Laborers, it is not necessary to determine which *particular* prescriptions would have been generic Asacol 400, only that at least *one* in their “group” of different patients’ purchases would have been generic Asacol 400.

Lexapro was not the first opinion in this circuit to endorse the use of statistical proof to prove injury to TPPs. As here, the drug manufacturer defendant in *Neurontin* argued that in order to prove their off-label marketing misconduct actually caused any particular prescription for TPP purchasers, the plaintiffs would have to provide individualized evidence from thousands of individual physicians. *Neurontin*, 712 F.3d at 63. The district court granted summary judgment to the defendant and denied class certification, finding that a “granular doctor-by-doctor analysis” was required. *Id.* at 65-66 (citation omitted). The First Circuit reversed summary judgment in favor of the defendant and vacated the denial of class certification, reasoning that the district court erred in finding that plaintiff’s aggregate statistical analysis, again provided by Dr. Rosenthal, was incapable of establishing TPP plaintiffs were injured by defendant’s conduct. *Id.* at 68-69. In rejecting defendant’s plea that individual testimony from thousands of doctors was necessary, the First Circuit held “the existence of these individual doctors does not defeat the implication—clearly presented through Dr. Rosenthal’s regression analysis—that Pfizer’s misinformation had a significant influence on thousands of other prescribing decisions. . . . Ultimately, it is a jury’s task to weigh the individual testimony presented by Pfizer against the aggregate and circumstantial evidence presented by the Harden plaintiffs.” *Id.*

The First Circuit has also been consistent in affirming *verdicts* based upon the use of aggregate statistical analysis to prove cause-in-fact and TPP injury. In *Kaiser*, a parallel case to *Neurontin*, the First Circuit upheld a jury verdict in the TPP plaintiff's favor and rejected defendant's challenges to the sufficiency of aggregate statistical proof. *Kaiser*, 712 F.3d at 45-47. There, Dr. Rosenthal again "use[d] aggregate data and statistical approaches" to link defendant's misconduct to prescription patterns. *Id.* at 29 (alteration in original) (citation omitted). In affirming Dr. Rosenthal's methodology, the First Circuit surveyed the well-established precedent "long permit[ing] parties to use statistical data to establish causal relationships." *Id.* at 42. And in *AWP*, citing Dr. Rosenthal's work, the First Circuit affirmed a class-wide antitrust verdict for TPP plaintiffs and affirmed the use of aggregate statistical analysis to prove that groups of prescription prices would have been lower than they were but for defendant's misconduct. *AWP*, 582 F.3d at 190.

So here; Plaintiffs have substantial statistical and circumstantial evidence to prove injury and cause-in-fact. To the extent Defendants believe they have admissible individual evidence capable of persuasively rebutting Plaintiffs' proof, they will be allowed to present it to a jury.

II. Named Plaintiffs have their own valid claims in Florida, Minnesota, and Wisconsin.

Wisconsin Masons has purchases and injury in Wisconsin; NECA-IBEW has purchases and injury in Wisconsin and Florida; and Minnesota Laborers has purchases and injury in Wisconsin and Minnesota. *See* Section I.B. Defendants' only challenges to these claims are that (1) Minnesota Laborers lacks data that can identify independent purchasers, and (2) NECA-IBEW's Florida claims are prohibited by the Florida statute because NECA-IBEW is not a Florida resident. D. Br. at 17-18. Both arguments fail.

First, Minnesota Laborers has unredacted data and has submitted that data. PSOF ¶ 105 (Exs. 100-01). *Second*, the Florida Deceptive and Unfair Trade Practices Act applies equally to protect citizens from other states that are injured *in Florida*, as NECA-IBEW was when it was overcharged for purchases *in Florida*. *Renaissance*, 738 So. 2d at 438-39 (upholding class claim under Florida law even where 92% of the tickets were sold to non-resident class members because, in part, the overcharge payments were made in Florida). Defendants' cases actually explain that location of injury is the correct inquiry, not "residency." *See Océ Printing Sys. USA, Inc. v. Mailers Data Servs., Inc.* 760 So. 2d 1037, 1042 (Fla. Dist. Ct. App. 2000) (rejecting nationwide class and application of Florida law to non-Florida residents with injuries *outside* Florida: "The only proper class is one whose members suffered an injury due to adverse effects *in the state of Florida* arising from a restraint on trade.") (emphasis added); *Coastal Physician Servs. of Broward Cty., Inc. v. Ortiz*, 764 So. 2d 7, 8 (Fla. Dist. Ct. App. 1999) (noting the Florida statute was for the protection of consumers who received offending billing notices *inside* Florida but would not extend to consumers who received offending billing notices *outside* Florida).

CONCLUSION

For all the foregoing reasons, Defendants' motion for summary judgment should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Nathaniel L. Orenstein, hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on June 17, 2019.

/s/ Nathaniel L. Orenstein
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